APPENDIX D
NASA/JSC HUMAN RESEARCH INFORMED CONSENT*

The following is from the *JSC Institutional Review Board Guidelines for Investigators Proposing Human Research for Space Flight and Related Investigations*, Space and Life Sciences Directorate (JSC-20483, Revision B).

1. I, the undersigned, do voluntarily give my informed consent for my participation as a test subject in the following research study, test, investigation, or other evaluation procedure:

NAME OF INVESTIGATION

_____

_____

FLIGHT TO WHICH ASSIGNED

_____

PRINCIPAL INVESTIGATOR

_____

RESPONSIBLE NASA PROJECT SCIENTIST

_____

I understand or acknowledge that:

(a) This procedure is part of an investigation approved by NASA.

(b) I am performing these duties as part of my employment with _____

(c) This research study has been reviewed and approved by the JSC Institutional Review Board (IRB) which has also determined that the investigation involves _____risk to the subject.
(minimal or reasonable)

(d) Definitions:

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Reasonable risk" means that the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but that

the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

(e) The research procedures were explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered to my satisfaction. A layman's description was provided to me. **

(f) I am medically qualified to participate in the investigation.

(g) I know that I can refuse to participate in the tests at any stage of their performance, and physician, termination of the tests could have detrimental consequences for my health and/or the health of the other subjects. I further understand that my withdrawal or refusal to participate in this investigation will not result in any penalty or loss of benefits to which I am otherwise entitled.

(h) In the event of physical injury resulting from this study and calling for immediate action or attention, NASA will provide or cause to be provided, the necessary treatment. I also understand NASA will pay for any claims of injury, loss of life or property damage to the extent required by the Federal Employees Compensation Act or the Federal Tort Claims Act. My agreement to participate shall not be construed as a release of NASA or any third party from any future liability which may arise from, or in connection with, the above procedures.

(i) Except as provided for by Agency-approved routine uses under the Privacy Act, the confidentiality of any data obtained as a result of my participation as a research subject in this study shall be maintained so that no data may be linked with me as an individual. I understand, however, that if a life-threatening abnormality is detected, the investigator will notify me and the JSC Flight Medicine Clinic. Such information may be used to determine the need for care or medical follow-up, which, in certain circumstances, could affect my professional (flight) status.

Signature: Signature:

_____ _____

Test Subject Date Witness Date

2. I, the undersigned, the Principal Investigator of the investigation designated above, certify that:

(a) I have thoroughly and accurately described the research investigation and procedures to the test subject and have provided him/her with a layman's description of the same.

(b) The test setup involves _____risk to the test subject. All equipment to be used
(minimal/reasonable)
has been inspected and certified for safe and proper operation.

(c) The test subject is medically qualified to participate.

(d) Except as provided for by Agency-approved routine uses under the Privacy Act, the confidentiality of any data obtained as a result of the test subject's participation in this study shall be maintained so the no data may be linked to him/her as an individual.

(e) The test protocol has not been changed f torn that originally approved by the JSC IRB.

Signature: Signature:

_____ _____

Principal Investigator Date NASA Project Scientist Date

Notes:

* This form is valid for the period including preflight in-flight, and postflight data collection sessions for the mission. Before the first baseline data collection, the Principal Investigator will repeat the briefing concerning risks involved in the investigation. A signed, dated copy of this form with attachments must be forwarded to Chairperson, Johnson Space Center Institutional Review Board, Attn: Dr. Lawrence Dietlein, Mail Code SA, Lyndon B. Johnson Space Center, Houston, Texas 77058.

** A detailed description of the investigation will be attached to this consent form. The Principal Investigator is responsible for formulating this document, which should be in layman's terms such that the subject clearly understands what procedures will be required of him/her and the risks associated therewith.

The detailed description of the research must, at a minimum, include the following:

(1) An explanation of the purposes of the research and the expected duration of the subjects participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject, including, but not limited to, possible adverse reactions of all medications to be administered and any risks/hazards resulting from exposure to ionizing radiation;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) Clarification of all forms of behavior, if any, interdicted by the research protocol (e.g., exercise, diet, medications, etc.); and

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

When appropriate, the following information shall also be provided in the detailed description:

(8) A statement that the particular treatment or procedure may involve links to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(9) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(10) Any additional costs to the subject that may result from participation in the research;

(11) The consequences of a subjects decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(12) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(13) The approximate number of subjects invoked in the study.

NASA/RSA HUMAN RESEARCH INFORMED CONSENT *

1. I, the undersigned, do voluntarily give my informed consent for my participation as a test subject in the following research study, test, investigation, or other evaluation procedure:

NAME OF INVESTIGATION

_____

_____

FLIGHT TO WHICH ASSIGNED

_____

PRINCIPAL INVESTIGATOR

_____

RESPONSIBLE NASA PROJECT SCIENTIST

_____

RESPONSIBLE RSA SCIENCE PROGRAM MANAGER

_____

I understand or acknowledge that:

(a) This procedure is part of an investigation approved by NASA/RSA.

(b) I am performing these duties as part of my employment with
_____

(c) This research study has been reviewed and approved by the JSC Institutional Review Board (IRB) and the Russian Biomedical Ethics Board which has also determined that the investigation involves _____risk to the subject.
(minimal or reasonable)

(d) Definitions:

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Reasonable risk" means that the probability and magnitude of harm or discomfort anticipated in the research are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, but that the risks of harm or discomfort are considered to be acceptable when weighed against the anticipated benefits and the importance of the knowledge to be gained from the research.

(e) The research procedures were explained to me prior to the execution of this form. I was afforded an opportunity to ask questions, and all questions asked were answered to my satisfaction. A layman's description was provided to me. **

(f) I am medically qualified to participate in the investigation.

(g) I know that I can refuse to participate in the tests at any stage of their performance and my refusal will be honored, except in those cases when, in the opinion of the responsible physician, termination of the tests could have detrimental consequences for my health and/or the health of the other subjects. However, understanding the significance of the investigations, (tests) I will give every effort to perform the full scope of the program.

(h) In the event of injury resulting from this study, I understand that I will receive immediate medical attention and necessary treatment. I also understand that I will be compensated for any injuries to the extent permitted under current U.S. and Russian laws and provisions of the contract between NASA and RSA. My agreement to participate shall not be construed as a release of NASA/RSA or any third party from any future liability which may arise from, or in connection with, the above procedures.

(i) Consistent with statutory and Agency-approved routine uses under the Privacy Act, the confidentiality of any data obtained as a result d my participation as a research subject in this study shall be maintained, so that no data may be linked with me as an individual. However, if a "life-threatening" abnormality is detected, the investigator will notify me and the JSC Flight Medicine Clinic. Such information may be used to determine the need for care or medical follow-up, which, in certain circumstances, could affect my professional (flight) status.

Signature:

_____

Test Subject Date

2. I, the undersigned, the Principal Investigator of the investigation designated above, certify that:

(a) I have accurately described the procedure to the test subject.

(b) The test setup involves _____ risk to the test subject. All equipment to
(minimal or reasonable)
be used has been inspected and certified for safe and proper operation

(c) The test subject is medically qualified to participate.

(d) The test protocol has not been changed from that originally approved by the JSC IRB and the Russian Biomedical Ethics Board.

Signature:

_____

Principal Investigator Date

Concurrence:

_____ _____

NASA Project Scientist Date RSA Science Program Manager Date

Notes:

*· This form is valid for the period including preflight, in-flight, and postflight data collection sessions for the mission. Before the first baseline data collection, the Principal Investigator will repeat the briefing concerning risks involved in the investigation. A signed, dated copy of this form with attachments must be forwarded to 1) Chair, Johnson Space Center Institutional Review Board, ATTN: Dr. Lawrence Dietlein, Mail Code SA, Lyndon B. Johnson Space Center. Houston, Texas 77058, and 2) The Institute for Biomedical Problems, ATTN: Dr. Abram Genin, Biomedical Ethics Commission, Khoroshevskoe shosse, 76A, Moscow, 123007, Russia.

** A detailed description of the investigation will be attached to this consent form. The Principal Investigator is responsible for formulating this document, which should be in layman's terms such that the subject clearly understands what procedures will be required and the risks associated therewith.

The detailed description of the research procedures must specifically list the risks associated with the procedures to be employed, the possible adverse reactions of all medications to be administered, and the risks/hazards resulting from exposure to ionizing radiation. Further, the investigator must clearly specify all forms of subject behavior interdicted by the research protocol (exercise, diet, medication, etc.).

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